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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/539,032	03/30/2000	Samir Kumar Brahmachari	KNS3.001AUS	7985

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/539,032	BRAHMACHARI ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Information Disclosure Statement

The IDS filed 7/3/06 has been considered in full.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Applicant's arguments filed 6/28/06 have been fully considered but they are not persuasive.

In response to the argument that steps vii) and viii) of original claim 1 provide support for comparison of *peptide* sequences, it is noted that applicant's admits on page 6 of the response that "step vii) "recites comparing pathogenic strain *genomes* against *genomes* of non-pathogenic strains" and that step viii) recited "searching for the given conserved sequences in the host *genome*." All of Merriam-Webster's Online Dictionary, the American Heritage Dictionary (online edition), and the Oxford English Dictionary Online agree that a genome consists of chromosomal or genetic material, specifically DNA or RNA. Nowhere did the examiner find a definition of a *genome* as

one comprising proteins or peptides, thus the argument that comparison of genomes, as recited in original claim 1, provides support for comparison of peptides is not persuasive. Applicant also points to Figure 1 wherein peptides of "any two organisms" may be compared, which organisms "can be bacteria or host." It is noted that the description of PEPLIMP (outlined in Figure 1) on page 2 of the specification indicates that PEPLIMP is designed to return a list of peptides which two organisms have IN COMMON, not those which differ. Further, the specification on pages 14-15 discloses that PEPLIMP is intended to run after PEPLIB but before PEPXTRACT and PEPSTSITCH; i.e. PEPLIMP performs steps equivalent to ii) and iii) of the claimed method. It is noted that Example 3 on page 15 explicitly states that the PEPXTRACT takes the output from PEPLIMP as input and locates and labels them. Thus, the overall disclosure indicates that PEPLIMP is one of comparing sequences to produce matched common or conserved (invariant) sequences, NOT to find different sequences. Further, nowhere does the specification or any of the Figures indicate that PEPLIMP is to be used to compare "host" and bacterial sequences. While organisms A and B of Figure 1 are not limited in the Figure to be bacterial sequences, nowhere is it disclosed that either A or B may be a host sequence. Given the disclosure of the specification on pages 2 and 14-16, one skilled in the art would NOT have been made aware that Figure 1 indicated comparison of extended conserved bacterial peptide sequences to host peptide sequences in order to determine those PEPTIDES which are not present in a host.

The argument that the invention "is clearly directed to comparison of the genomes at the peptide level" is not persuasive. As set forth above, a "genome" does not comprise peptides. It is recognized that many genes encode peptides/proteins; however, it is well known in the art of both molecular biology and biochemistry that not all genes encode peptides or proteins; some encode tRNA, nucleic acid regulatory elements, and other non-peptide products. In addition, it is well known that some genes encode multiple peptides/proteins. Thus, a comparison of genomes is not inherently a comparison of peptides. In addition, given the redundancy of nucleic acid codons encoding amino acids in addition to alternative splicing, etc., a comparison of peptides is not necessarily a comparison of genomes. Thus, the implied argument that comparison of genomes is the same as, or inherently includes, comparison of peptides is not persuasive.

For these reasons and those previously set forth, the examiner maintains that the claims recite new matter, and the rejection is maintained.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Any rejections previously made under 35 USC 112, 2nd paragraph not maintained below are hereby withdrawn in view of the amendment filed 6/28/06.

Claims 5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites increasing the number of conserved peptide sequences "by increasing the relatedness" among organisms. It is unclear what is meant by this phrase; i.e. reducing the number of organisms being compared such that those remaining are of "increased relatedness" compared to those removed; or considering only those with a specified (high) degree of relatedness; or actually mutating organisms such that they become more "related", or some other manipulation of organisms and/or data. As the step intended is unclear, the claim is indefinite.

In the response filed 6/28/06, applicant points to page 14 of the specification which indicates that a mixture of pathogenic and non-pathogenic organisms produces fewer invariant peptides than does pathogenic organisms only or nonpathogenic organisms only. Applicant is reminded that the rejection is not one of enablement or written description, but one of definiteness. It is unclear what meaning/limitation is intended *by applicant* for the phrase "increasing the relatedness." Does applicant intend removal of certain organismal types from a database? Or perhaps, applicant intends to ADD organisms to a database in order to increase the average "relatedness" among those organisms? What sort of "relatedness" is intended - e.g. functional, physical, etc? The specification does not provide a definition nor specific guidance for what is intended by "increasing the degree of relatedness." Page 14 of the specification discloses only a comparison, but does not define either "relatedness" nor "increasing

the relatedness." As it is still unclear what is intended by this phrase, the rejection is maintained.

Applicant is reminded that any amendment must be fully supported and enabled by the originally filed disclosure.

Claim 8 recites the limitation "the selected organism" in the last line. There is insufficient antecedent basis for this limitation in the claim. Parent claim 1 recites a plurality of "selected organisms" in steps (i) and (iii), therefore it is unclear what single "organism" is intended as the antecedent basis for "the organisms" of claim 8. In response to applicant's arguments filed 6/28/06, it is appreciated that applicant has attempted to overcome the rejection by amendment. However, it is noted that claim 1 does provide support for multiple "selected organisms"; however, claim 8 recites only one. It is still unclear whether the single "selected organism" is one of the plurality of claim 1 or is a new one; e.g. one found within the database but not necessarily one used to generate the matched common peptide sequences of step (iii). As the intended antecedent basis of "the selected organism" is still unclear, the rejection is maintained.

Conclusion

Claims 1-9 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Monday-Friday; 6 am-2:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
9/17/06